

COD-123

UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.

First Named Inventor or Application Identifier

HongHua Cao

Express Mail Label No.

EL32726488US

(only for new nonprovisional applications under 37 CFR 1.53(b))

APPLICATION ELEMENTS

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

See MPEP Chapter 600 concerning utility patent application contents.

1. ☒ Fee Transmittal Form (attached hereto in duplicate)
2. ☒ Specification [Total Pages 8]
(Preferred arrangement set forth below)
 - Descriptive Title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 USC 113) [Total Sheets 2]
4. Oath or Declaration
 - a. ☐ Newly executed (original or copy)
 - b. ☒ Unexecuted original
 - c. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional check boxes 5 and 16)
 - i. ☐ Deletion of Inventor(s)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation by Reference
(useable if Box 4c is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4c, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy) *in*
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PAPER

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement
(when there is an assignee) ☐ Power of Attorney
10. ☐ English Translation Document (if applicable)
11. ☐ Information Disclosure Statement
(IDS)/PTO-1449 ☐ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)

15. ☐ Other:16. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:Amend the specification by inserting before the first line: — This is a ☐ Continuation ☐ Divisional☐ Continuation-in-Part (CIP) of prior application No.:

17. For this divisional application, please cancel original Claims

, filed
of the prior application before calculating the filing fee.

18. CORRESPONDENCE ADDRESS

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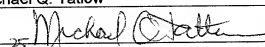
19. TELEPHONE CONTACT

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Fax: (732) 524-2808

19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Michael Q. Tatlow	Reg. No. 20501
SIGNATURE		
DATE	May 26, 2000	

05/25/00

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SLIT TIP VENTRICULAR CATHETER

This invention is directed to an improvement in a ventricular catheter to prevent a slit at the distal end of the catheter from adhering together or knitting during sterilization or storage.

Background of the Invention

Ventricular catheters are widely used in various procedures including the collection of cerebrospinal fluid, introduction of contrast medium or chemotherapy, the measurement of intracranial pressure and the treatment of hydrocephalus. The proper positioning of the catheter in the ventricular system is facilitated by the use of a rigid stylet or the use of an optical endoscope.

The catheters are generally constructed of silicone elastomer tubing and have a series of fluid flow apertures adjacent the distal end and a slit at the distal end. The slit is capable of opening to permit the terminal end of a stylet or optical endoscope to pass through the slit to properly position the catheter. When the catheter is in the desired position in the ventricle, the stylet or optical endoscope can be removed while leaving the catheter in position. These types of catheters are disclosed in U.S. Patents 5,437,626;

5,690,117 and 5,738,666, the disclosures of which are incorporated herein by reference.

One of the difficulties in the use of slit catheters is the tendency of the edges of the catheter adjacent the slit be adhered together or knit together during sterilization or storage and close the slit so that a stylet or optical endoscope cannot be passed through the slit to aid in positioning of the catheter.

Summary of the Invention

The present invention is directed to an improved slit tip ventricular catheter that is constructed and packaged in a manner to prevent the slit tip from knitting or the edges adhering together during sterilization or storage.

The present invention accomplishes this desirable result by inserting a thin inert tab into the slit when the catheter manufactured and retaining the tab in the slit until the catheter is used. At the time of use, the tab is removed from the slit and the catheter is used in the normal manner. Ventricular catheters of the present type are usually packaged in a sterile package and are mounted on a paper board insert.

Brief Description of the Drawings

In the drawings:

Fig. 1 shows the distal portion of a ventricular catheter.

Fig. 2 shows the distal portion of a ventricular catheter with a stylet or endoscope in the distal end.

Fig. 3 shows a slit tip catheter of the present invention with a tab positioned in the slit.

Fig. 4 shows a slit tip catheter mounted on a paper board holder in a sterile package.

Fig. 5 shows the details of the preferred film tab of the present invention.

Detailed Description of the Invention

As shown in Fig. 1, a slit tip ventricular catheter 10 has a tubular body 11 and a number of fluid flow apertures 12 in the distal portion 13 of the tubular body. There is a slit 14 in the distal tip 15 of the catheter.

As shown in Fig. 2, if a stylet or optical endoscope 16 is pushed against the slit 14, the slit will open to

allow the stylet or optical endoscope to pass through the distal tip catheter to aid in positioning the catheter.

Ventricular catheters are commonly constructed of a biologically compatible plastic material such as a silicone elastomer, commonly referred to as siliastic. The opposed edges of the slit at the distal end of the catheter are in contact with each other during sterilization and subsequent storage until use. The opposed edges of the slit have a tendency to adhere to each other or knit together. When this knitting occurs, it is difficult and sometimes impossible to force a stylet or optical endoscope through the slit. The catheter must then be removed from the patient and the procedure reinitiated with a different ventricular catheter.

The present invention avoids the aforementioned problem by inserting an inert tab into the slit after the catheter is manufactured and before it is packaged and sterilized. When the catheter is to be used, it is removed from the sterile package and the tab is removed before the catheter placed in use. The tab prevents the opposed edges of the catheter from adhering to each other.

The tab may be made of any inert plastic or paper that can be sterilized and which is compatible with the

material from which the catheter is constructed. The tab should be thin enough, about 1 to 3 mils, so that it does not cause a set or gap in the slit when the tab is removed. A thickness of 1 mil or less is preferred. A polyester film having a thickness of 0.92 mil has been found to give excellent results.

As shown in Fig. 3, the tab 17 fits into the slit with an excess of material 18 extending beyond the slit so that the tab can be aseptically removed from the slit in the operating room.

The film tab may be simply inserted into the slit and the catheter packaged for sterilization. However, to prevent the inadvertent removal or loss of the film tab from the slit during processing or storage, a package construction as shown in Fig. 4 may be used.

As shown in Fig. 4, in the preferred construction of the present invention, the catheter is mounted on a paper board card 19 for packaging. A small rectangular piece of a clear polyester film about 1 inch by 7/8 inch and 0.92 mil thick is secured to the paper board card by a hypoallergenic pressure-sensitive adhesive. Adhesives used are generally hypoallergenic, latex-free, pressure-sensitive adhesives. Adhesives that are preferred are silicone medical adhesives such as SMA available from Dow Corning and MED-1137 available from Nusil Technology.

The film has a free distal end toward the distal end of the catheter and a proximal end which is secured to the paper board holder with the adhesives.

5 As best shown in Fig. 5, there is a C-shape or three sided cut in the middle of the film that provides a flap in the film. A flap 17 is formed at the free end of the film and is inserted into the slit in the distal end of the catheter to prevent knitting. The excess material 18 at the end of the flap allows the catheter to be aseptically removed from the paper board holder 19. The flap 18 can be held and the catheter 10 removed from the holder which separates the film 17 from the slit 14 in the catheter. Securing the film to the paper board card prevents the tab from accidentally falling free of the slit prior to using the catheter. As indicated above, the thinness of the film prevents the slit taking a set and remaining open after the tab is removed.

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CLAIMS

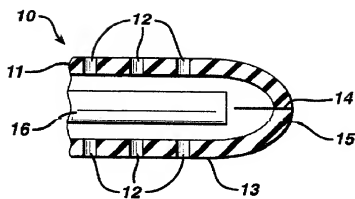
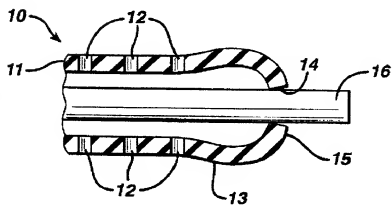
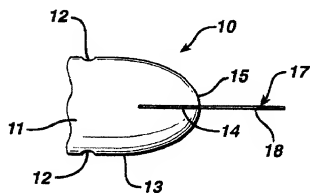
What is claimed is:

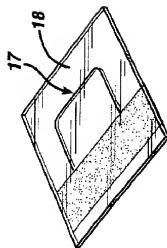
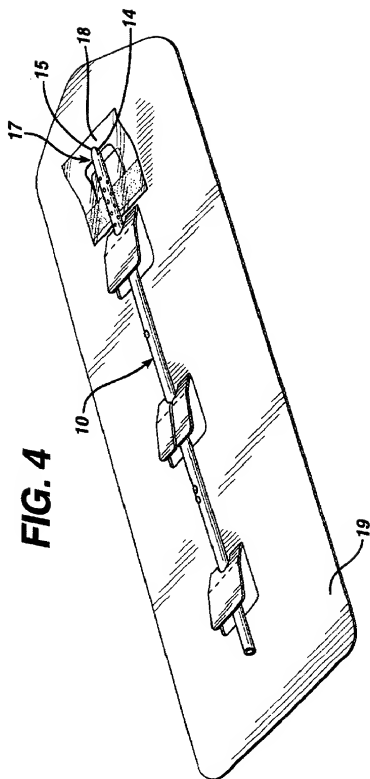
- 5 1) A sterilizable ventricular catheter having a proximal end and a distal segment having a plurality of drainage holes and a closed distal end formed with a slit, said slit being movable between a closed configuration and an open configuration, a (sterilizable) removable film tab inserted into the slit to prevent the edges of the slit from knitting together during sterilization and storage.
- 10
- 15 2) The catheter of Claim 1 in which the distal end of the catheter is removably affixed to a paper board holder and one end of the film tab is adhesively secured to the holder.
- 20 3) The catheter of Claim 1 in which the film tab has a proximal end and a distal end, said proximal end of the tab being adhesively secured to said holder and the distal end having a flap which is positioned in the slit in the catheter.
- 25 4) The catheter of Claim 2 in which the film tab is a polyester film having a thickness of about 1 mil.

SLIT TIP VENTRICULAR CATHETER

Abstract

5 A ventricular catheter of the type having a slit in the
distal end to permit the passage of a stylet or endoscope
is disclosed. The catheter is packaged with a film tab
inserted into the slit to prevent the edges of the slit
from knitting or adhering to each other upon
10 sterilization or storage.

FIG. 1**FIG. 2****FIG. 3**



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled SLIT TIP VENTRICULAR CATHETER, the specification of which

(check one) ☒ is attached hereto.

☐ was filed on _____ as

Application Serial No. _____

and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119	
			<input type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number)

(Filing Date)

(Application Number)

(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.

Filing Date

Status

Application Serial No.

Filing Date

Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Audley A. Ciamporcero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194), Michael Stark (Reg. #32,495), Joseph F. Shirtz (Reg. #31,880), and Michael Q.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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or First Inventor

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Inventor, If Any

Date: _____

Citizenship:

Residence:

Post Office Address:

Inventor's Signature: _____

Full Name of Third Joint
Inventor, If Any

Date: _____

Citizenship:

Residence:

Post Office Address:

(Supply similar information and signature for fourth and subsequent joint inventors.)